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APP. NO. 08/670,119 FIRST NAMED INVENTOR 06/25/96 NG

G SIM-001(7434

EXAMINER

18M1/0429

PATENT ADMINISTRATOR  
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BOSTON MA 02110

APPROVED BY PAPER NUMBER

1818

DATE MAILED: 04/29/97

This is a communication from the examiner in connection with your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

*For Restriction ONLY*

- ☒ This application has been examined ☒ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-59 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-59 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_, filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-17, drawn to a method of inhibiting function of an integral membrane protein comprising contacting the integral membrane protein with a peptide, classified in Class 435, subclass 7.2.
  - II. Claims 18-37, drawn to a method of preventing or treating a disorder in a mammal characterized by disordered function of an integral membrane protein comprising administering a peptide, classified in Class 514, subclass 2.
  - III. Claims 38-37, drawn to an antagonist for an integral membrane protein that includes peptides, classified in Class 530, subclass 300.
2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups I-II are directed to methods of inhibiting function of an integral membrane protein and methods of treating a mammal for disorders characterized by altered function of an integral membrane protein. Each of the methods require physically and functionally distinct elements. For

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example, the use of peptides in a method to inhibit integral membrane function, as in Group I, involves entirely different considerations related to labeling agents for detecting inhibition of integral membrane protein function, versus the different considerations necessary in the method of Group II, which requires a mammal with a integral membrane disorder, along with effective dosages and effective modes of administering peptides, which are not required in the method of Group I, and vice versa. These inventions are, therefore, patentably distinct, since one is not required for the other.

Inventions III and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptide antagonist molecules of Group III can be used in other materially different diagnostic methods, such as identifying specific membrane proteins within a cell, or can be used to generate antibodies against themselves. The method of inhibiting function of integral membrane proteins of Group I requires appropriate labeling protocols for detection of the test compounds, which are not required for the products of Group III. The method of Groups II requires mammalian patients with specific disorders, which are not required for the products of Group III.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of

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the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. A telephone call was made to michael Twomey on 3/14/97 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
April 28, 1997



MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1818